510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k052914

B. Purpose for Submission:
New device

C. Measurand:
Potassium, Chloride, Sodium, and Magnesium

D. Type of Test:
Quantitative, Photometric and Ion-specific

E. Applicant:
RANDOX LABORATORIES, LTD.

F. Proprietary and Established Names:
RX Imola

G. Regulatory Information:

1. Regulation section:
   21CFR §-862.1600-Potassium test system.
   21CFR §-862.1170-Chloride test system.
   21CFR §-862.1665-Sodium test system.
   21CFR §-862.1495-Magnesium test system.
   21CFR §-862.2160-Discrete photometric chemistry analyzer for clinical use.

2. Classification:
   Class 2

3. Product code:
   CEM - electrode, ion specific, potassium
   CGZ - electrode, ion-specific, chloride
   JGS - electrode, ion specific, sodium
   JGJ - photometric method, magnesium
   JJE - analyzer, chemistry (photometric, discrete), for clinical use

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   The RX Imola is a medium-sized desktop fully Automated Clinical Chemistry

Analyzer complete with Ion Selective Electrode (ISE) Unit and dedicated analyzer software. An external PC operates the analyzer and results can be printed as required. The analyzer may be connected to a host computer, when required.

The analyzer can be used to run tests such as magnesium in serum and plasma samples. Magnesium measurements are used in the diagnosis and treatment of hypomagnesaemia and hypermagnesaemia. Various other clinical chemistry assays are adaptable to the analyzer.

The ISE Unit on the RX Imola can be used for measurement of the electrolytes sodium, potassium and chloride in serum, plasma and urine and for use in diagnosis and treatment of electrolyte imbalance.

The RX Imola analyzer must only be used by suitably qualified personnel, under appropriate laboratory conditions.

For in vitro diagnostic use only.

2. Indication(s) for use:
   See 1. above.

3. Special conditions for use statement(s):
   For prescription use

4. Special instrument requirements:
   RX Imola analyzer

I. Device Description:

The RX Imola contains an ISE module for the measurement of Potassium, Chloride, Sodium, cleared under k024014 and a wet chemistry module. The cleared Randox Magnesium assay k974606 is submitted for use on the RX Imola

The RX Imola is a bench-top fully automated random access clinical analyzer. The RX Imola has the capacity to perform up to 400 tests per hour plus ISEs, and offers primary tube sampling, on-board sample dilution and a cooled reagent compartment.

- Cuvette wash system
- Refrigerated sample carousel for on-board calibrators and QC material
- STAT facility
- Direct interface with hose computer
- Automatic re-run and pre-dilution functions

The RX imola™ uses dedicated software for easy access to all system facilities and functions. A color, graphic user interface guides through the operating functions and provides a comprehensive data management system.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Randox RX Daytona Analyzer with ISE
   Randox Magnesium

2. Predicate 510(k) number(s):
   k024014 and k974606 respectively

3. Comparison with predicate:

Similarities and Differences Analyzer Only		
Item	Predicate	Device
Intended use	Same	Same
Assay types	End-point, kinetic, turbidimetric, ISE, sample and reagent blanking.	Same
Calibration types	Linear, Factor, 2 point, point to point, log-logit, spline and exponential	Same
Calibration system	Up to 7 calibrators, and pre-dilution facility	Same
Sample types	Serum, plasma, urine, CSF, and supernatant	Same
Throughput	450 test per hour (180 photometric and 270 ISE)	560 tests per hour (400 photometric and 240 ISE)
Software	External PC and Windows NT based user interface	Same
Reaction system	45 reusable Pyrex cuvettes (500 ul max volume)	90 reusable Pyrex cuvettes (500 ul max volume)
Stirring System	Stick type rotating stirrer with variable speed	Same
Sample input	40 position routine, STAT and QC samples. Barcode ID, Pre-dilution and auto re-assay	Two concentric ring disks for sample cup: Outer ring 72, inner ring 20 positions for calibrators, controls and STATS. Barcode ID, Pre-dilution and auto re-assay.
Sample Pipette	Micropipette with level detector. Inside and outside water wash	Same
Sample volume	2-35ul	Same
Reagent System	Onboard refrigeration, barcode ID, calculation of remaining reagents and tests. 40 reagent positions.	Onboard refrigeration, barcode ID, calculation of remaining reagents and tests. 60 reagent positions.

Similarities and Differences Analyzer Only		
Item	Predicate	Device
Reagent Pipette	Micropipette with level detector. Inside and outside water wash	Same
Reagent volume	20-400ul	R1 20-350ul R2 20-250ul
Reaction system	Direct heating 37 C +/- 0.3	Same
Wavelengths	340, 380, 415, 510, 546, 570, 600, 700 nm	340, 380, 415, 510, 546, 570, 600, 660, 700, 750, 800 nm
ISE	Optional	Standard
Electrode Type	Sodium, Potassium, Chloride and Reference	Same
ISE Throughput	Serum – 90 urine 36 per hour	Serum – 80 urine 32 per hour
ISE Sample size	70ul serum (70ul x3) 50ul urine	Same
ISE calibration	Two point calibration	Same

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Randox Magnesium Assay

Magnesium ions react with xylidyl blue in an alkaline medium to form a water soluble purple-red chelate, the color intensity of which is proportional to the concentration of magnesium in the sample. Calcium is excluded from the reaction by complexing with EGTA

The ISE unit measures the concentration of sodium (Na), potassium (K) and chloride (CI) contained in serum, plasma, urine etc. by using ion specific electrodes. Urine must be diluted ten times before measurement.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Precision studies were performed using control materials at three concentrations for serum and two concentrations for urine. Testing was conducted in duplicate for 11 days with two runs per day. The results are summarized in the tables below.

Magnesium

Within run precision (Serum)	Level 1	Level 2	Level 3	**Total run precision (Serum)**	Level 1	Level 2	Level 3
Mean (mg/dL)	1.60	2.19	4.23	Mean (mg/dL)	1.60	2.19	4.23
SD	0.024	0.049	0.049	SD	0.024	0.049	0.073
CV(%)	1.6	1.7	1.2	CV(%)	2.2	2.2	1.6
n	44	44	44	N	44	44	44

Magnesium

Within run precision (Urine)	Level 1	Level 2	**Total run precision (Urine)**	Level 1	Level 2
Mean (mg/dL)	7.07	38.1	Mean (mg/dL)	7.07	38.1
SD	0.10	0.37	SD	0.10	1.19
CV(%)	1.2	1.0	CV(%)	1.5	3.1
N	44	44	n	44	44

Sodium

Within run precision (serum)	Level 1	Level 2	Level 3	**Total run precision (serum)**	Level 1	Level 2	Level 3
Mean (mmol/L)	116.13	138.00	153.51	Mean (mmol/L)	116.13	138.00	153.51
SD	0.33	0.48	1.28	SD	0.79	1.18	1.93
CV (%)	0.3	0.3	0.8	CV (%)	0.7	0.9	1.3
N	42	44	42	N	42	44	42

Sodium

Within run precision (urine)	Level 1	Level 2
Mean (mmol/L)	65.83	185.61
SD	1.94	1.76
CV (%)	2.9	0.9
N	44	44

Total run precision (urine)	Level 1	Level 2
Mean (mmol/L)	65.83	185.61
SD	2.73	5.37
CV (%)	4.1	2.9
N	44	44

Potassium

Within run Precision (serum)	Level 1	Level 2	Level 3	**Total run precision (serum)**	Level 1	Level 2	Level 3
Mean (mmol/L) SD	3.05 0.01	4.02 0.02	5.96 0.03	Mean (mmol/L) SD	3.05 0.12	4.02 0.16	5.96 0.35
CV (%) N	0.4 44	0.5 44	0.4 44	CV (%) N	4.0 44	4.0 44	5.9 44

Potassium

Within run precision (urine)	Level 1	Level 2	**Total run precision (urine)**	Level 1	Level 2
Mean (mmol/L) SD	28.59 0.56	91.02 1.27	Mean (mmol/L) SD	28.59 2.12	91.02 3.26
CV (%) N	2.0 40	1.4 40	CV (%) n	7.4 40	3.6 40

Chloride

Within run precision (serum)	Level 1	Level 2	Level 3	**Total run precision (serum)**	Level 1	Level 2	Level 3
Mean (mmol/L) SD	86.03 0.26	97.34 0.32	115.04 1.79	Mean (mmol/L) SD	86.03 1.72	97.34 1.32	115.04 2.06
CV (%) N	0.3 44	0.3 44	1.6 43	CV (%) N	2.0 44	1.4 44	1.8 43

Chloride

Within run precision (urine)	Level 1	Level 2	**Total run precision (urine)**	Level 1	Level 2
Mean (mmol/L) SD	69.80 1.64	210.57 2.58	Mean (mmol/L) SD	69.80 4.05	210.57 6.79
CV (%) N	2.3 44	1.2 44	CV (%) n	5.8 44	3.2 44

b. Linearity/assay reportable range:

Linearity studies were performed to determine the analytical range of an assay – that is the range where the reported result is a linear function of the analyte concentration (or where deviation from linearity is less that 5%).

The linearity samples were prepared at 9 levels. The sponsor used a range from 0 analyte concentration (or other reasonable bottom of range level) up to a high concentration approximately 10% greater than the upper level of linearity to be claimed for the method.

Analyte	Linearity	
	mg/dL	mmol/L
Magnesium (serum)	6.02	3.30
ISE Sodium (serum)		170
ISE Potassium (serum)		11
ISE Chloride (serum)		200
Magnesium (urine)	60	25.0
ISE Sodium (urine)		1100
ISE Potassium (urine)		450
ISE Chloride (urine)		1100

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* See k955489 calibrator and k942458 control for Mg and k024014 for ISE

d. *Detection limit:*

Analyte	Limit of Detection		Limit of Quantification	
	mg/dL	Mmol/L	mg/dL	mmol/L
Magnesium (serum)	0.05	0.02	0.435	0.18
ISE Sodium (serum)	N/A*	N/A		28.4
ISE Potassium (serum)	N/A	N/A		0.33
ISE Chloride (serum)	N/A	N/A		54.45
*N/A = Not Applicable				
Magnesium (urine)	0.05	0.02	1.80	0.74
ISE Sodium (urine)	N/A	N/A		23.0
ISE Potassium (urine)	N/A	N/A		5.87
ISE Chloride (urine)	N/A	N/A		32.7

e. *Analytical specificity:*

The analytes below were tested in serum up to the following levels and were found not to interfere with magnesium:

	Low Pool	High Pool
Hemoglobin	250 mg/dL	750 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugate Bilirubin	30 mg/dL	30 mg/dL
Triglycerides	1000 mg/dL	1000 mg/dL
Intralipids®	250 mg/dL	250 mg/dL

The analytes below were tested in urine up to the following levels and were found not to interfere with magnesium:

	Low Pool	High Pool
Hemoglobin	1000 mg/dL	1000 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugate Bilirubin	30 mg/dL	30 mg/dL
Triglycerides	1000 mg/dL	1000 mg/dL
Intralipids	1000 mg/dL	1000 mg/dL

ISE - Serum
Analytes were added to the normal serum and were found not to interfere with ISE up to the following levels:

Sodium	Low Pool	High Pool
Hemoglobin	1000 mg/dL	1000 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugated Bilirubin	30 mg/dL	30 mg/dL
Triglycerides	500 mg/dL	750 mg/dL
Intralipids	500 mg/dL	500 mg/dL
Potassium	Low Pool	High Pool
Hemoglobin	0 mg/dL	0 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugated Bilirubin	30 mg/dL	30 mg/dL
Triglycerides	1000 mg/dL	1000 mg/dL
Intralipids	500 mg/dL	500 mg/dL
Chloride	Low Pool	High Pool
Hemoglobin	1000 mg/dL	1000 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugated Bilirubin	30 mg/dL	30 mg/dL
Triglycerides	500 mg/dL	500 mg/dL
Intralipids	500 mg/dL	500 mg/dL

Urine
Analytes were added to normal urine and were found not to interfere up to the following levels:

Sodium	Low Pool	High Pool
Hemoglobin	1000 mg/dL	1000 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugated bilirubin	30 mg/dL	30 mg/dL
Triglycerides	250 mg/dL	750 mg/dL
Intralipids	750 mg/dL	1000 mg/dL
Potassium	Low Pool	High Pool
Hemoglobin	0 mg/dL	500 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugated bilirubin	30 mg/dL	30 mg/dL
Triglycerides	1000 mg/dL	1000 mg/dL
Intralipids	500 mg/dL	1000 mg/dL
Chloride	Low Pool	High Pool
Hemoglobin	1000 mg/dL	1000 mg/dL
Free Bilirubin	30 mg/dL	30 mg/dL
Conjugated bilirubin	30 mg/dL	30 mg/dL
Triglycerides	500 mg/dL	1000 mg/dL
Intralipids	1000 mg/dL	1000 mg/dL

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

Magnesium
This method (Y) was compared with another commercially available method. (X) 106 serum patient samples were analyzed spanning the range 0.7 to 7.6 mg/dL and the following linear regression equation was obtained:
Y = 1.01 X - 0.09 and a correlation coefficient of r = 0.997.
43 urine patient samples were analyzed spanning the range 2.2 to 58.1 mg/dL and the following linear regression equation was obtained:
Y = 0.98 X + 0.41 and a correlation coefficient of r = 0.997.

Sodium
This method (Y) was compared with another commercially available method. (X) 62 serum patient samples were analyzed spanning the range 83.9 to 161.0 mmol/L and the following linear regression equation was obtained:
Y = 0.917 – 11.24 and a correlation coefficient of r = 0.982.
41 urine patient samples were analyzed spanning the range 63.8 to 852.0 mmol/L and the following linear regression equation was obtained:
Y = 1.007 – 7.03 and a correlation coefficient of r = 1.000.

Potassium
This method (Y) was compared to another commercially available test method. (X) 66 serum patient samples were analyzed spanning the range 2.4 to 15.2 mmol/L. and the following linear regression equation was obtained:
Y = 0.96 X + 0.13 and a correlation coefficient of r = 1.000.
42 urine patient samples were analysed spanning the range 36.8 to 450.6 mmol/L and the following linear regression equation was obtained:
Y = 0.96 X + 3.55 and a correlation coefficient of r = 0.999.

Chloride
This method (Y) was compared to another commercially available test method. (X) 62 serum patient samples were analyzed spanning the range 57.3 to 188.9 mmol/L and the following linear regression equation was obtained:
Y = 1.03 X - 0.87 and a correlation coefficient of r = 0.995.
40 Urine patient samples were analyzed spanning the range 80.4 to 470.7 mmol/L and the following linear regression equation was obtained:
Y = 0.96 X - 9.22 and a correlation coefficient of r = 0.984.

b. Matrix comparison:
Matrix method comparisons for all assays using both serum and lithium heparin plasma were conducted to determine whether method accuracy with lithium heparin plasma specimens are equivalent to serum results and that lithium heparin plasma does not interfere with either the method or the system.

Patient samples were drawn in matched pairs - one sample serum (y) and the second sample lithium heparin plasma (x). A minimum of 20 matched patient sample pairs were tested using only the method under evaluation.

Analyte	Regression	r	(n)
Magnesium	y = 1.004x + 0.00	0.992	25
ISE Sodium	y = 0.983x + 0.96	0.984	23
ISE Potassium	y = 0.954x + 0.23	0.974	24
ISE Chloride	y = 0.972x + 1.81	0.990	24

3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable

   b. Clinical specificity:
   Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable

4. Clinical cut-off**:**
   Not Applicable

5. Expected values/Reference range:
   Referenced from literature

N. Instrument Name:

RX Imola Analyzer

O. System Descriptions:

1. Modes of Operation:

   - Software Windows XP based
   - Random access and STAT modes
   - Test channels 63 channels (60 photometric channels, 3 ISEs)
   - Assay types Endpoint, kinetic, turbidimetric, ISE, sample and reagent blanking
   - Reagent system- 60 reagent positions. Barcode identification of reagents, calculation of remaining reagent volume and tests available.
   - Integrated ISE unit
   - Cuvette system - 90 reusable cuvettes (volume 150 uL min, 450 uL max)
   - Detector - Direct absorbance in cuvette (mono or bi-chromatic). Filters for 340, 380, 415, 450, 510, 546, 570, 600, 660, 700, 750 and 800 nm

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X___ or No _____

   The applicant has provided software documentation typical for this device type which demonstrates the device was developed and is currently under good software lifecycle processes.

3. Specimen Identification:

   Barcode ID

4. Specimen Sampling and Handling:

   Blood collection tubes, Sample cups STATS, Pre-dilution and auto re-assay

5. Calibration:

   Linear, Factor, 2 point, point to point, log-logit, spline and exponential

6. Quality Control:

   Quality Control database, with various QC analysis functions.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.